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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/889,227 | 01/08/2002 | Bernd Riedl | BAYER 15(1) | 5714 |
| 23599 7590 01/22/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | EXAMINER DESAI, RITA J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/22/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/889,227

Applicant(s)

RIEDL ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6-10, 18-27, 33-40, 42, 44, 45, 50, 53-55, 58, 59, 62, 64, 65, 68-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/24/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1,3,4,6-10,18-27,33-40,42,44,45,50,53-55,58,59,62,64,65 and 68-72.

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DETAILED ACTION

Claims pending 1, 3, 4, 6-10, 18-27, 33-40, 42, 44, 45, 50, 53-55, 58, 59, 62, 64, 65, 68-72.

Claims amended are 62, 64, 65, 70 and 72.

The IDS mailed 5/25/06 has been viewed and initialed.

The IDS scanned in on 6/01/06 includes the remaining references of the 1449 mailed 5/24/06.

The rejection of claims 62, 64 and 65 under 35 USC 112 second paragraph has been withdrawn as applicants have amended the claims.

The rejection of claims 70 and 72 under 35 USC 112 first paragraph still stands.

The examiner is now including the claims 55, 58, 59, 62, 64, 65 and 68 under 35 USC 112 first paragraph enablement.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to

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make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention: The invention is to treat cancer.

The state of the prior art: There is very little known in the treatment of cancer.. The state of the prior art is that it involves screening in vitro and invivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability and no established correlation between in vitro activity and the treatment of any and all cancers as the in vitro data is not a reliable predictor of success even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The level of one of ordinary skill: The ordinary artisan is highly skilled.

The level of predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. The level of unpredictability in the art is very high. The compounds which differ by a methyl group also show different properties, for e.g. theophylline and caffeine. One of them is a bronchodilator and they differ only by a methyl group. And also the method of treating cancer let alone a specific cancer is not predictable. The state of the art clearly indicates that one drug cannot treat all the various types of cancer , which are in different tissues.

The amount of direction provided by the inventor: The inventor provides **no direction**

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direction in the instant specification. There are no examples of the compositions used to treating cancerous growth let alone solid tumors. No examples that inhibit the raf kinase enzyme also. They no test nor any data that the compounds do have the activity that applicants claim.

The existence of working examples: The instant specification **does not have any working** examples.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure is very high as there are no examples given that these compounds do have the raf-kinase activity, the amount of experimentation is very high and burdensome.

Taking the above factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instantly claimed invention. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Double Patenting rejection Arguments :-

Applicants state The subject application was filed before copending applications US 10/361,858, 10/361,859,10/308,187 and 10/895,985 and is therefore, the "earlier filed

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application" under MPEP 804 (I)(B) with respect to each of these applications. Based on the procedures set forth in MPEP 804 (I)(B), the nonstatutory "provisional" obviousness-type double patenting rejections based on these applications should be withdrawn without filing a terminal disclaimer in the subject application.

Applicants traverse the provisional obviousness-type double patenting rejection based on claims 1-15 of copending application US 10/071,248. Claims 1- 15 of this application are directed to specific urea compounds which require hydroxy substituents or ester substituents based on the proviso that "at least one of XI to X7 of formula I is OH or -OC(O)C1-C4 alkyl." The compounds claimed herein do not have hydroxy or ester groups at the positions corresponding to XI to X7 of formula I within US 10/071,248. Applicants submit such compounds do not render the compounds claimed herein obvious. The examiner has not provided any evidence of motivation to eliminate the required substituents of the compounds claimed in US 10/071,248 to arrive at the compounds claimed herein.

Applicants will cancel the claims on which the rejection is based in copending applications 09/948,915 (claim 61) and 10/086,417 (claim 12) and submit copies of these amendments in supplemental submissions. Applicants will also file a terminal disclaimer in the subject application naming copending applications US 0/042,203 and US 09/993,647 once the obviousness-type double patenting rejection based on copending application 10/071,248 is overcome.

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With respect to US 10/361,858, 10/361,859, 10/308,187 and 10/895,985, the rejection is dropped as it is the earlier filed application.

With respect to 09/948,915 (claim 61) and 10/086,417 (claim 12) application will cancel the claims and file a copy to indicate that.

With respect to US 00/042,203 and US 09/993,647 applicants state that they will file a TD once the DP issue regarding 10/071,248 is resolved.

Applicants arguments for the DP 10/071,248 has been considered but not found to be persuasive, as the hydroxyl or ester substituent has not been enabled in the co-pending application and identical compounds are disclosed in both the specifications and hence it still reads on the claims of the instant invention.

Conclusion

The claims 1, 3, 4, 6-10, 18-27, 33-40, 42, 44, 45, 50, 53-55, 58, 59, 62, 64, 65, 68-72 are still not found to be allowable.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625


1/12/07

R.D.
January 12, 2007